

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

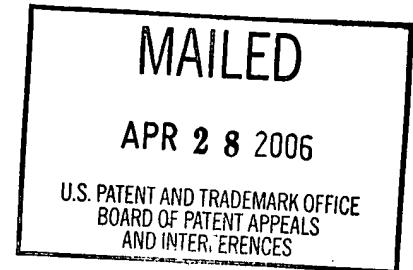
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOYCE BEDELIA B. SANTOS,
RITA JOSEFINA M. SANTOS, and KENNIE U. DEE

Appeal No. 2006-0251
Application No. 10/017,697

ON BRIEF



Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-20, 22-24, 26, 28-33 and 43-46. Of the remaining pending claims, the examiner has indicated (Answer, page 3) claims 35-42 are allowable (Answer, page 3), and claims 21, 25, 27 and 34 stand objected to as dependent on a rejected claim.¹ As appellants indicate (Brief, page 2), "the [e]xaminer indicated that claims 21, 25, 27 and 34 ... would be allowable if written in independent form, including all of the limitations of the base claim and any intervening claims." See e.g., Answer, page 12.

¹ The objection to claim 21, 25, 27 and 34 is not before us on this appeal.

Claims 1 and 5 are illustrative of the subject matter on appeal and are reproduced below:

1. A taste-masked liquid pharmaceutical composition or extemporaneously prepared liquid pharmaceutical composition, comprising:
at least one unpleasant tasting drug;
polyethylene glycol of molecular weight at least 900, and
polyvinyl pyrrolidone and/or copolyvidone,
wherein a final form of said taste-masked pharmaceutical composition administered to a patient is a liquid.
5. The liquid pharmaceutical composition according to [c]laim 1, wherein the amount of polyethylene glycol is from about 0.05 to about 10 weight percent.

The reference relied upon by the examiner is:

White 5,431,916 Jul. 11, 1995

GROUNDS OF REJECTION

Claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 stand under 35 U.S.C. § 102(b) as anticipated by White.

Claim 5, 6, 9, 12, 14 and 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over White.

We reverse.

DISCUSSION

The present invention relates to a taste-masked liquid pharmaceutical composition. Specification, page 1. According to appellants' specification (*id.*), "[t]he unpalatable taste of most drugs is generally not a problem with solid

dosage formats, which are intended to be swallowed whole.” However, as appellants’ specification points out (*id.*), “[m]any children and some adults … have difficulty swallowing solid dosage formats, and in this case, the drug is given in liquid form, either as a syrup or suspension.” This, however, can lead to poor patient compliance because most drugs are bitter. *Id.* In this regard, appellants’ specification discloses (*id.*), “[b]ecause the threshold for bitterness is low, only a very small amount of dissolved drug is needed for perception of bitterness.” Accordingly, appellants disclose a “general solution to the problem of bad taste in liquid compositions containing either dissolved or dispersed drugs.” Specification, page 2. In this regard, appellants disclose (specification, bridging paragraph, pages 2-3), “[t]he drug is dissolved or dispersed in an aqueous taste masking excipient base comprising a high molecular weight (MW) polyethylene glycol, a polyvinyl pyrrolidone and/or copolyvidone.” According to appellants’ specification (page 3), the resulting composition has substantially reduced bitter taste and aftertaste.

Against this backdrop, we consider the merits of the pending rejections.

Anticipation:

Claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 stand under 35 U.S.C. § 102(b) as anticipated by White. The examiner relies on White to teach a composition within the scope of appellants’ claimed invention. In this regard, we find that White discloses pharmaceutical compositions that contain

essential, non-essential² and optional components. According to White, the disclosed pharmaceutical compositions comprise three essential components:

1. tri-esters, such as triethyl citrate and glyceryl triacetate (column 3, lines 21-64);
2. polyvinylpyrrolidone (column 3, line 65 – column 5, line 20); and
3. at least one pharmaceutically acceptable active.

As optional components, Whites pharmaceutical compositions may also include polyethylene glycol (column 6, line 41 – column 7, line 31) and/or water (column 7, lines 32-46). According to the examiner, White discloses polyethylene glycol having molecular weight of from about 300 to about 4,600. Answer, page 3.

According to the examiner (Answer, page 4), since the transitional term "comprising"³ does not exclude tri-esters, White discloses a composition that meets all the limitations of the rejected claims. A claim is anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 USPQ 1264, 1270 (Fed.Cir.1984); Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed.Cir.1983); Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir.1983).

² According to White (column 6, lines 25-40), nonessential components include, inter alia, solubilizing agents, colorings surfactants, and flavorings".

³ The transitional term "comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added, and still result in a composition within the scope of the claim. Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

While White discloses both liquid (column 7, line 47 – column 8, line 12), and soft gelatin capsule (column 8, line 13 – line 10, line 3) formulations⁴, White discloses (column 1, lines 26-29, emphasis added), “[s]oft gelatin capsules are a preferred dosage form for accurately dispensing liquids, offering a simple means of masking the unpleasant taste and aromas of many pharmaceutically acceptable actives.” We find, and the examiner identifies, no teaching in White of a taste-masked liquid pharmaceutical composition. Accordingly, it appears the examiner is relying on the principles of inherency to reach appellants’ claim the limitation that the final form of the taste-masked pharmaceutical composition is a liquid.

However, as set forth in In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” As we understand the examiner’s reasoning at page 10 of the Answer, since White discloses a composition that comprises pyrrolidone and a high MW polyethylene glycol, White’s composition will, like appellants’ composition, result in a taste-

⁴ In this regard, we note that White exemplifies several liquid pharmaceutical formulations that are “suitable for oral administration, and encapsulation within soft gelatin shells.” See Examples I, III-V, VII, and VIII. Example VIII, however, is the only example that contains a drug, polyethylene glycol, polyvinylpyrrolidone, and a tri ester. Accordingly, we find White’s Example VIII to be the closest to appellants’ claimed invention.

masked liquid pharmaceutical composition. Compare, appellants' disclosure (specification, page 4), "[i]n the present invention, the normally bitter drug is dissolved or dispersed in an aqueous taste masking excipient base comprising a polyvinyl pyrrolidone and/or copolyvidone, and a high MW polyethylene glycol. The taste masked liquid composition has substantially reduced bitter taste and aftertaste." According to the examiner (Answer, page 10), "[i]f polyethylene glycol and polyvinylpyrrolidone are taste-masking agents in the instant case, the polyethylene glycol and polyvinylpyrrolidone will also mask the taste of the bitter or unpleasant tasting drug [in White]."

Based on the foregoing analysis, we find the examiner provided the evidence necessary to establish a prima facie case of anticipation based on inherency. Accordingly, the burden shifts to appellants to "prove that the subject matter shown to be in the prior art does not possess the characteristic relied on."

In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971). Accord In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980), quoted with approval in In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir.1985); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977); In re Lutke, 441 F.2d 660, 664, 169 USPQ 563, 566 (1971).

According to appellants (Brief, page 6), a tri-ester is an essential component of White's composition. In this regard, appellants point out (id.) that tri-esters have a bitter taste. Accord White, column 3, lines 22-23, "[t]ri-esters are generally clear, viscous liquids with a bitter taste and low toxicity." Thus, appellants assert (Brief, page 6), "the compositions disclosed by White contain

tri-esters and therefore have a substantially bitter taste (due at least in part to the presence of the tri-ester), which is not masked and therefore is perceptible by a patient." In support of this assertion appellants direct attention to the Dee Declaration, received April 30, 2004. According to Dee (Declaration, paragraph 14), as illustrated in Exhibit 2 attached to the Declaration, testing in Dee's "laboratory determined that the compositions of White are unacceptably bitter."

In response, the examiner argues (Answer, page 11), "[t]he instant composition does not exclude the presence of tri-esters. The exhibit does not present a parallel example where the tri-ester of White is included in the instant composition. The tasting experiment thus focused on the composition of the prior art and not on the instant composition, which does not exclude tri-esters." We cannot agree with the examiner's assertion. According to Dee (Exhibit 2, page 1), "a pharmaceutical composition containing acetaminophen was prepared according to the composition and process described in White's Example VIII." As discussed above (n. 4), White exemplifies several liquid pharmaceutical formulations of which only Example VIII exemplifies a composition that contains a drug, polyethylene glycol, polyvinylpyrrolidone, and a tri ester. Accordingly, White's Example VIII is the "parallel example" the examiner appears to be asking for, wherein the tri-ester of White is included in appellants' claimed composition, which comprises a drug, polyethylene glycol and polyvinyl pyrrolidone. As set forth in Dee (Declaration, paragraph 14, and Exhibit 2, page 1), the composition was "unacceptably bitter." Thus, the evidence of record establishes that White's

composition cannot anticipate appellants' taste-masked liquid pharmaceutical composition.

Accordingly, we reverse the rejection of claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 under 35 U.S.C. § 102(b) as anticipated by White.

Obviousness:

Claim 5, 6, 9, 12, 14 and 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over White. Each of claims 5, 6, 9, 12, 14 and 20 depend ultimately from and further limit claim 1, to a recited amount of polyethylene glycol, polyvinylpyrrolidone, and sweetening agents, as set forth in claims 5, 6, 9, 12 and 14; or to the inclusion of specific antibiotics, as set forth in claim 20. While the examiner recognizes that White does not teach the limitations of claim 5, 6, 9, 12, 14 and 20, the examiner nevertheless maintains that they would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made. The examiner, however, does not rely on any additional evidence to supplement the teachings of White.

As discussed above, White teaches a composition (see e.g., claim 1) that differs from the claimed invention only in the inclusion of a tri-ester as an essential component of the composition. In addition, as discussed above, the evidence of record establishes that the essential tri-ester is bitter and renders a composition comprising a drug, polyethylene glycol and polyvinyl pyrrolidone unacceptably bitter. The examiner provides no evidence, and therefore has not established, that it would have been prima facie obvious to a person of ordinary

skill in the art at the time the invention was made to prepare White's composition in the absence of the essential tri-ester, and thereby arrive at a composition such as that set forth in appellants' claim 1. Accordingly, the examiner has not met his burden⁵ of providing the evidence necessary to establish that claim 1 is prima facie obvious over White. Since claims 5, 6, 9, 12, 14 and 20 ultimately depend from claim 1, we find that the examiner has failed to meet his burden of establish a prima facie case of obviousness for these claims as well.

Accordingly, we reverse the rejection of claim 5, 6, 9, 12, 14 and 20 under 35 U.S.C. § 103 as being unpatentable over White.

REVERSED

Toni R. Scheiner)
Toni R. Scheiner)
Administrative Patent Judge)
Donald E. Adams) BOARD OF PATENT
Donald E. Adams)
Administrative Patent Judge)
Demetra J. Mills) APPEALS AND
Demetra J. Mills)
Administrative Patent Judge)
INTERFERENCES)

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⁵ In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

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